RECORD AND BRIEFS

No. 15-1195

Supreme Court, U.S.
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IN THE

Supreme Court of the United States

AMGEN INC. AND AMGEN MANUFACTURING LIMITED,

Cross-Petitioners,

v.

SANDOZ INC.,

Cross-Respondent.

ON CROSS-PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

REPLY BRIEF FOR THE CONDITIONAL CROSS-PETITIONERS

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of the Rules of this Court, Respondents Amgen Inc. and Amgen Manufacturing Limited state the following:

Amgen Inc. is a publicly held corporation. Amgen Inc. has no parent corporation and no publicly held corporation owns 10% or more of its stock.

Amgen Manufacturing Limited is a wholly owned subsidiary of Amgen Inc. Apart from Amgen Inc., there is no publicly held corporation with a 10% or greater ownership in Amgen Manufacturing Limited.

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ARGUMENT

Amgen's cross-petition is conditional. Because the provisions of the BPCIA on which Sandoz and Amgen each petition for review use identical language in an integrated statutory scheme, the interpretation of one bears on the interpretation of the other. The Court should review them together, if at all.

Sandoz recasts Amgen's question presented, to argue that this Court would have to reach questions of state law to avoid an advisory opinion. The Federal Circuit's resolution of Amgen's state-law claims, however, turned on federal law, not state law. It held that those claims failed in relevant part because they rested on Amgen's construction of subparagraph 262(*l*)(2)(A) of the BPCIA, which the Federal Circuit rejected. (*See* Pet. App. at 26a-29a.) The Federal Circuit also decided Sandoz's counterclaims for declaratory judgments regarding the rights and remedies available under the BPCIA where an Applicant refuses to provide the subparagraph 262(*l*)(2)(A) disclosure. The Federal Circuit directed the district court "to enter judgment on those counterclaims consistent with [the Federal Circuit's] opinion" and its "interpretation of the BPCIA." (*See id.* at 3a-4a, 31a.)

There is a ripe, federal-law controversy between Sandoz and Amgen about the meaning of subparagraph 262(*l*)(2)(A), which this Court can resolve without venturing into state-law issues.

I. SANDOZ OFFERS NO REASON WHY THIS COURT SHOULD REVIEW ONLY ONE COMPONENT OF AN INTEGRATED STATUTE, RATHER THAN BOTH

Sandoz argues that Amgen's conditional cross-petition does not meet the Court's certiorari standards, and that the question presented is not sufficiently important to warrant review. (Sandoz Opp'n ("Opp'n") at 4; *see also id.* at 23.) To be sure, Supreme Court Rule 12.5 requires that a cross-petition "comply in all respects with this Rule and Rule 14." Amgen met that requirement and Sandoz makes no effort to demonstrate otherwise.

The question, then, is not compliance with the rules, but whether this Court should accept both petitions if it accepts either. The issues raised by Sandoz's and Amgen's petitions are inextricably intertwined. (*See* Cross-Pet. at 8, 22-25.) Both 42 U.S.C. § 262(*l*)(2)(A) and § 262(*l*)(8)(A) are triggered by the Applicant's choice to seek FDA licensure under the subsection (k) pathway, rather than the traditional approval pathway. Both state that the Applicant "shall provide" specific things, yet differently composed majorities of the Federal Circuit panel construed one "shall" as mandatory and one as optional. (*See* Pet. App. at 12a-18a, 23a-26a.) Thus, Amgen's cross-petition is no less important than the petition on which it is contingent.

Sandoz's arguments confirm that the Court should treat the two petitions in tandem. Sandoz asserts that the Federal Circuit erred by treating

subparagraph 262(*l*)(8)(A) as a "standalone" provision, "disconnecting the notice provision from the BPCIA's patent resolution regime." (Pet. at 22.) And in opposing Amgen's cross-petition, Sandoz argues that the word "shall" in subparagraph 262(*l*)(2)(A) must be understood in the context of subsection 262(*l*) as a whole. (Opp'n at 21.)

The parties agree that the provisions of subsection 262(*l*) are an integrated series of steps. Thus, if the Court determines that the construction of subparagraph 262(*l*)(8)(A) is ripe for review and that this case is the proper vehicle to grant Sandoz's petition, the Court should also grant Amgen's cross-petition on the proper construction of subparagraph 262(*l*)(2)(A), so that these related provisions of an integrated statute can be construed in the context of subsection 262(*l*) as a whole.

II. SANDOZ OFFERS NO TENABLE DEFENSE OF THE FEDERAL CIRCUIT'S TREATMENT OF "SHALL" AS OPTIONAL

Sandoz's ten-page argument that "the BPCIA does not require a biosimilar applicant to disclose its application to the sponsor in all circumstances," (Opp'n at 1, 2-3, 14-23), cannot change the simple and clear statutory command. When an Applicant submits an application for FDA approval under the abbreviated pathway of subsection 262(k), as Sandoz did, it "shall provide . . . the information required to be produced [its aBLA and manufacturing information] pursuant to" paragraph 262(*l*)(2). 42 U.S.C. § 262(*l*)(1)(B)(i). And, paragraph 262(*l*)(2) in turn expressly states that

"[n]ot later than 20 days after" FDA notifies the Applicant that its aBLA "has been accepted for review," the Applicant "shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application," and that the Applicant "may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor." 42 U.S.C. § 262(*l*)(2)(A), (B). In holding that the Applicant is not required to provide the subparagraph 262(*l*)(2)(A) information, the Federal Circuit erred.

This Court's precedents are clear that the verb "shall" is generally mandatory, and that where "shall" is used in juxtaposition to the verb "may"—as it is here—the "shall" is clearly mandatory. (*See* Cross-Pet. at 26 (citing *Nat'l Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 661-62 (2007); *Jama v. Immigration & Customs Enf't*, 543 U.S. 335, 346 (2005); *Lopez v. Davis*, 531 U.S. 230, 241 (2001); *Anderson v. Yungkau*, 329 U.S. 482, 485 (1947); *United States ex rel. Siegel v. Thoman*, 156 U.S. 353, 359-60 (1895)).)

Sandoz now argues that the distinction between "shall" and "may" in paragraph 262(*l*)(2) is not that one is mandatory and the other optional, but that one is a "condition precedent to proceeding to the next step of the patent exchange process" and the other is not. (Opp'n at 20.)

While it is true that several of the steps after subparagraph 262(*l*)(2)(A) depend on the Applicant providing its aBLA and manufacturing information, that does not make provision of that information optional. The only conditions precedent to providing that information, as the statute states expressly, is an Applicant's submission of its aBLA under subsection (k) and notification by FDA that the application has been accepted for review. 42 U.S.C. § 262(*l*)(1)(B)(i), (*l*)(2)(A). Congress did not say that an Applicant that wishes to initiate the patent-exchange procedures "shall" provide its aBLA and manufacturing information, while an Applicant that chooses, or opts, or elects not to initiate the process may decline to provide that information. On the contrary, Congress gave Applicants the choice of electing the new abbreviated pathway of subsection (k) and the attendant obligations that arise under subparagraph 262(*l*)(2)(A), or filing their FDA applications through the traditional 262(a) pathway without triggering such obligations. Indeed, Sandoz's opening assertion that the BPCIA does not require disclosure "in all circumstances" is curious (Opp'n at 1), because Sandoz never identifies <u>any circumstance</u> in which it contends that disclosure is required.

The surrounding statutory context further confirms that the "shall" in subparagraph 262(*l*)(2)(A) mandatory. In at least four places, the BPCIA refers to provision of the aBLA and manufacturing information as "required," and twice refers to non-provision of that information as a "fail[ure]." *See* 42 U.S.C. § 262(*l*)(1)(B)(i), (*l*)(9)(A),

(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii). Sandoz acknowledges, as it must, that the statute consistently uses "required" when referring to actions that "shall" be performed under 262(*l*)(2)(A), but not to those that "may" be performed pursuant to 262(*l*)(2)(B). (*See* Opp'n at 20.)

Sandoz also has no valid response to the consequences of its own argument. As Amgen showed in its cross-petition, there is a mandatory injunction under the BPCIA where a Sponsor prevails on a patent in a paragraph 262(*l*)(6) lawsuit while the Sponsor is within the data-exclusivity period of paragraph 262(k)(6). (*See* Cross-Pet. at 29-30 (citing 35 U.S.C. § 271(e)(4)(D)).) If an Applicant can choose not to provide its aBLA and manufacturing information, it can prevent the Sponsor from bringing a paragraph 262(*l*)(6) lawsuit and thus deprive the Sponsor of this remedy. Sandoz argues that a paragraph 262(*l*)(6) lawsuit during the 262(k)(6) exclusivity period "will rarely occur," and further argues that the injunction in 35 U.S.C. § 271(e)(4)(D) cannot be mandatory despite its plain text. (Opp'n at 22.) The Federal Circuit found the opposite, that "aBLAs will often be filed during the 12-year exclusivity period." (Pet. at 22a.) That Sandoz's statutory interpretation would render an express injunctive remedy a dead letter confirms that Sandoz is wrong.

The statutory purpose also confirms that subparagraph 262(*l*)(2)(A) is mandatory. (*See* Cross-Pet. at 27-31.) The BPCIA requires manufacturing patents to be included in the patent-dispute procedures, *see* 42 U.S.C. § 262(*l*)(3), yet

without the Applicant's aBLA and manufacturing information the Sponsor would likely have no way of knowing which, if any, of its manufacturing patents would be infringed by the Applicant's (nearly always secret) manufacturing processes. (*See* Cross-Pet. at 28.) Sandoz's only answer to this is to suggest that "Competitors rarely have access to each other's confidential manufacturing processes before litigating" yet file infringement suits. (Opp'n at 21.) But that, too, ignores the statutory text. Congress explicitly made patents that cover the "making" of the biological product part of the patent lists and information provisions of paragraph 262(*l*)(3). That is why Congress required the Applicant to provide not only its aBLA but also "such other information that describes the process or processes used to manufacture the biological product." 42 U.S.C. § 262(*l*)(2). That this requirement is unusual, or even unique, in patent law is a reason to enforce the statute, not to render it optional.

Finally, Sandoz argues that where the Applicant refuses to provide the subparagraph 262(*l*)(2)(A) disclosures, the Sponsor's exclusive remedies are a declaratory judgment action under subparagraph 262(*l*)(9)(C) or a patent-infringement suit under 35 U.S.C. 271(e)(2)(C)(ii). As explained in Amgen's cross-petition, neither of these provisions is remedial, much less an exclusive remedy. (*See* Cross Pet. at 32-38.) Sandoz's argument depends on 35 U.S.C. § 271(e)(4), which provides the exclusive remedies "[f]or an act of infringement described in paragraph (2)." (emphasis added). But failing to provide the aBLA and manufacturing information is

not an act of infringement, and in suggesting otherwise the Federal Circuit erred. Before the BPCIA was enacted, Congress had made it "an act of infringement to submit" to the FDA an application under the Federal Food, Drug, and Cosmetic Act (most prominently, an Abbreviated New Drug Application). *See* 35 U.S.C. § 271(e)(2)(A), (B). The BPCIA extended this "act of infringement" to applications submitted under the Public Health Service Act seeking approval of a biological product. Thus, each of 35 U.S.C. § 271(e)(2)(C)(i) and (ii) states that "[i]t shall be an act of infringement to submit . . ., an application." The words that precede the comma determine which patents are infringed; the act of infringement is submitting an application. In a patent-infringement action on that technical act of infringement, section 271(e)(4) limits the available remedies for that infringement, as it does in the Hatch-Waxman Act context. That does not mean, however, that the remedies in section 271(e)(4) are the only remedies for a violation of the BPCIA.

Sandoz muddies the waters by arguing that the technical act of infringement in 35 U.S.C. § 271(e)(2)(C)(ii) is necessary to allow a declaratory judgment action. (Opp'n at 28.) Sandoz misapprehends the law. The technical act of infringement in section 271(e)(2) is not necessary to create declaratory-judgment jurisdiction. Rather, "section 271(e)(2) makes it possible for the district court to exercise its section 1338(a) jurisdiction." *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1330 (Fed. Cir. 2003) (citing *Glaxo, Inc. v.*

Novopharm, Ltd., 110 F.3d 1562, 1569 (Fed. Cir. 1997)). The dictum in the case Sandoz cites, *Glaxo Group. Ltd. v. Apotex, Inc.*, 376 F.3d 1339 (Fed. Cir. 2004), does not change this settled law. Subparagraph 262(*l*)(9)(C) lifts the limitation imposed on the Sponsor by subparagraph 262(*l*)(9)(A) and 28 U.S.C. § 2201(b): bringing "any" declaratory judgment action on specified patents. This limitation is not specific to declaratory judgment actions based on section 271(e), nor does it exclude actions based on anticipated future infringement under section 271(a), (b), (c), (g) or (f).

In holding that section 271(e)(4) sets forth the exclusive remedies for an Applicant's failure to provide its aBLA and manufacturing information, the Federal Circuit erred. If this Court is inclined to review the portion of the Federal Circuit's decision challenged by Sandoz's petition, it should grant Amgen's cross-petition and review this aspect of the decision as well.

III. SANDOZ WRONGLY ASSERTS THAT THE FEDERAL CIRCUIT'S DECISION RESTED ON INDEPENDENT STATE-LAW GROUNDS

Sandoz argues that reversal of the Federal Circuit's construction of the BPCIA would be an "advisory opinion" unless this Court were also to reach questions of state law. (Opp'n at 1.) Sandoz asserts that the Federal Circuit rejected Amgen's Cal. Bus. & Prof. Code § 17200 claim and conversion claim on both federal and state-law grounds. (*Id.* at 1, 2, 3, 25-26.)

That is not what happened. The Federal Circuit affirmed the dismissal of Amgen's state law claims "based on [its] interpretation of the BPCIA," including subparagraph 262(*l*)(2)(A). (Pet. App. at 26a.) That is, because the Federal Circuit held that subparagraph 262(*l*)(2)(A) does not require an Applicant to provide its aBLA and manufacturing information, Sandoz did not violate that provision, and the court affirmed the dismissal of Amgen's state-law claims, both of which depended on a violation of federal law. (*See id.* at 27a-30a.)

In addition, the court's interpretation of subparagraph 262(*l*)(2)(A) as optional rested on its conclusion that subparagraph 262(*l*)(9)(C) is remedial because it creates consequences for non-compliance with subparagraph 262(*l*)(2)(A). (*See id.* at 16a-17a.) The court further relied on the patent-infringement provision and remedies of 35 U.S.C. § 271(e)(2)(C)(ii) and (e)(4). (*See id.* at 18a.) It concluded that Amgen could not state a Section 17200 claim precisely because the court held that federal law—35 U.S.C. § 271(e)(4) and 42 U.S.C. § 262(*l*)(9)(C)—provides an exclusive remedy for Sandoz's failure to provide its aBLA and manufacturing information under subparagraph 262(*l*)(2)(A). (*See id.* at 27a.) While Sandoz relies on the Federal Circuit's statement that California law bars a Section 17200 remedy where the underlying statute itself provides a remedy (Opp'n at 26-30; Pet. App. at 27a), there was no independent state-law ruling there; the Federal Circuit's decision about California law turned entirely on its construction of the BPCIA.

Likewise, with respect to Amgen's conversion claim, Sandoz seeks to find a state-law ground of decision in the Federal Circuit's holding that Amgen did not have "an *exclusive* right to possession of its approved license on Neupogen to sustain its claim of conversion under California law." (Pet App. at 29a; Opp'n at 12.) But that, too, was a holding about federal law. The Federal Circuit relied on the BPCIA provisions permitting an Applicant to reference the Sponsor's license and a Sponsor's period of data exclusivity. (*See* Pet App. at 29a (citing 42 U.S.C. § 262(k)(2), (k)(7)(A)).)

Finally, Sandoz argues that "there are additional alternative state law grounds to affirm dismissal of Amgen's conversion claim," citing its brief in the Federal Circuit for arguments about intangible property rights under California law. (Opp'n at 31.) The Federal Circuit did not reach any of those arguments, and Amgen does not seek their review here. If there are unique state-law issues following from a construction of the BPCIA by this Court that require resolution on remand, they can be addressed by the Federal Circuit or district court.

All that Amgen's cross-petition asks this Court to review is the Federal Circuit's holding that subparagraph 262(*l*)(2)(A) is optional even though it provides that the Applicant "shall" provide "required" information. That is a holding about a federal statute, in violation of this Court's precedent. It is not a state-law issue at all.

IV. SANDOZ'S ARGUMENTS ABOUT PRIVATE RIGHTS OF ACTION AND ITS OWN COUNTERCLAIMS ARE NO BASIS TO GRANT ONLY SANDOZ'S PETITION

Sandoz makes two final arguments opposing Amgen's cross-petition.

First, Sandoz argues that even if Amgen were right about subparagraph 262(*l*)(2)(A), Amgen waived the separate question of whether the BPCIA provides a implied federal right of action. (*See* Opp'n at 29-30.)

This is a defense to an argument Amgen never made. Amgen's cross-petition does not, and need not, depend on its assertion of a private right of action. There is no private-right-of-action issue here. (*See* Amgen Opp'n to Sandoz's Pet. at 28-29.)

Second, Sandoz argues that its counterclaims provide no basis to review Amgen's supposedly "abstract" BPCIA arguments. (Opp'n at 32-34.) That is incorrect. Sandoz's counterclaims sought a declaration of the rights of the parties where an Applicant refuses to provide the information under subparagraph 262(*l*)(2)(A). (*See* Pet. App. at 64a.) That was not an "abstract" dispute; Sandoz refused to provide that information to Amgen. The Federal Circuit interpreted the BPCIA to permit non-disclosure of that information (*id.* at 18a), and directed the district court to enter judgment on Sandoz's counterclaims consistent with that statutory interpretation. (*Id.* at 4a, 31a.) Sandoz's

counterclaims thus squarely present the question in Amgen's cross-petition.

To that end, if this Court were to grant Amgen's cross-petition, reverse the Federal Circuit, and hold that subparagraph 262(*l*)(2)(A) is mandatory, the Federal Circuit and the district court could address any further questions of remedy on remand. There are unlikely to be any such issues, as Sandoz's argument has always been that the BPCIA permits Applicants to decline to provide that information. If this Court holds that Sandoz is wrong, it is hard to imagine Sandoz (or any other Applicant) flouting this Court's holding.

If the Court is not inclined to take both Sandoz's petition and Amgen's conditional cross-petition, the best course is to deny both. There are other BPCIA cases percolating in the district courts and before the Federal Circuit. They may well be better vehicles than this case. But if this Court is inclined to grant Sandoz's petition, it should grant Amgen's cross-petition too. None of Sandoz's arguments provides any basis to review only half of the Federal Circuit's decision.

CONCLUSION

This Court should deny Sandoz's Petition in No. 15-1039 for the reasons set forth in Amgen's brief in opposition. But if this Court grants Sandoz's Petition, it should also grant Amgen's Conditional Cross-Petition.

Respectfully submitted,

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